Application No.: NEW Docket No.: 3493-0170PUS1

AMENDMENTS TO THE CLAIMS

- 1. (Currently amended) Vinflunine pharmaceutical composition, wherein characterized in that it is in the form of a stable and sterile aqueous solution of a water-soluble vinflunine salt at a pH of between 3 and 4.
- (Currently amended) Composition according to Claim 1, wherein characterized in that the vinflunine salt is vinflunine ditartrate.
- (Currently amended) Composition according to Claim 2, wherein eharacterized in that the composition consists of vinflunine ditartrate and water for an injectable preparation.
- 4. (Currently amended) Composition according to Claim 1 or 2, wherein characterized in that it comprises a pH buffer system in order to maintain the pH between 3 and 4.
- (Currently amended) Composition according to Claim 4, wherein characterized in that the molarity of the pH buffer system is between 0.002 M and 0.2 M.
- 6. (Currently amended) Composition according to either of Claims 4 and 5, wherein characterized in that the pH buffer system consists of an acetic acid/sodium acetate buffer or a citric acid/sodium citrate buffer.

3 ADM/smt

Application No.: NEW Docket No.: 3493-0170PUS1

7. (Currently amended) Composition according to any one of Claims 2 to 6, wherein characterized in that the composition contains vinflunine ditartrate with a base vinflunine concentration of between 1 and 50 mg/ml, advantageously between 25 and 30 mg/ml and in particular 25 mg/ml.

- 8. (Currently amended) Composition according to any one of Claims 2 to 7, wherein characterized in that it corresponds to one of the following formulations: 68.35 mg of vinflunine ditartrate qs 2 ml in water or 136.70 mg of vinflunine ditartrate qs 4 ml of water or 341.75 mg of vinflunine ditartrate qs 10 ml of water, the vinflunine ditartrate corresponding, respectively, to 50 mg of base vinflunine, 100 mg of base vinflunine and 250 mg of base vinflunine.
- 9. (Currently amended) Composition according to any one of the preceding claims 1, wherein characterized in that it remains stable for at least 36 months at 5°C+3°C.
- 10. (Currently amended) Method for treating cancer comprising the parenteral administration of an effective amount Use of a composition according to any one of Claims 1 to 9 to a patient in need thereof, for the manufacture of a medicinal product for parenteral administration, advantageously via intravenous perfusion.
- 11. (Canceled).

4 ADM/smt

Application No.: NEW Docket No.: 3493-0170PUS1

12. (Currently amended) Process for preparing a composition according to any one of Claims1 to 9, comprising the following successive steps:

- (a) dissolution of the vinflunine salt in water for injectable preparations,
- (b) optional addition of a pH buffer,
 - (c) sterilization by filtration of the bulk solution,
 - (d) aseptic distribution, under a nitrogen atmosphere, of the sterile composition obtained in step (c) in the container, advantageously chosen from glass phials, glass bottles and prefilled syringes.
- 13. (Currently amended) Packaging container containing the composition according to any one of Claims 1 to 9.
- 14. (New) Composition according to claim 7, wherein it contains vinflunine ditartrate with a base vinflunine concentration of between 25 and 30 mg/ml.
- 15. (New) Composition according to claim 14, wherein it contains vinflunine ditartrate with a base vinflunine concentration of 25 mg/ml.
- 16. (New) Method for treating cancer according to claim 10, wherein the parenteral administration is via intravenous perfusion.

5 ADM/smt